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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,649	10/27/2003	Hanson S. Gifford III	020979-002310US	3982
20350 7590 08/14/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER KAHELIN, MICHAEL WILLIAM	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 08/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/695,649

Applicant(s)

GIFFORD ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-24 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 21, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20, 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 2-10, 21, 23, and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/23/2007.
2. Applicant's election without traverse of claims 11-20 and 22 in the reply filed on 5/23/2007 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 13 recites the limitation "the heart region". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3762

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 11, 13, 18, 19, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Walsh et al. (US 6,902,522, hereinafter "Walsh").

8. In regards to claims 11 and 18, Walsh discloses a method for treating congestive heart failure (col. 2, lines 14-27) comprising placing/introducing a band having a first and second end around a beating heart and drawing the first and second ends toward each other (col. 8, lines 20-29 and col. 10, lines 7-21).

9. In regards to claim 13, the band adheres to the heart (col. 8, line 54).

10. In regards to claim 19, the band is introduced at or below the AV groove (col. 7, line 65).

11. In regards to claim 22, treating CHF comprises treating mitral regurgitation (col. 14, line 45).

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3762

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 12 and 14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Walsh. Walsh discloses the essential features of the claimed invention, including that the claimed device/method can be applied to patients who have suffered MI (col. 14, line 11) and that the band is elastic (col. 11, line 61). Since Walsh's device surrounds the heart, the two ends (that are attached together at implantation) are on opposite sides of infarcted tissue, and since the band is elastic, it is a spring element. Alternatively, Walsh discloses the essential features of the claimed invention except for explicitly disclosing that the first and second ends of the band are on opposite sides of an infarcted region, and that the elastic element is a spring. It is well known in the art to provide compression bands to opposite sides of infarcted areas to reduce the replacement of infarcted tissue with scar tissue and provide mechanical stability to the dead tissue, and to provide springs in heart compression devices to allow for tight contact with the heart over the variable-volume heart cycle. Therefore, it would have been obvious to one having ordinary skill

Art Unit: 3762

in the art at the time the invention was made to provide Walsh's invention a compression band on opposite sides of an infarcted area to reduce the replacement of infarcted tissue with scar tissue and provide mechanical stability to the dead tissue, and to provide a spring to allow for tight contact with the heart over the variable-volume heart cycle.

15. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh. Walsh discloses the essential features of the claimed invention except for explicitly disclosing a subxiphoid approach for implanting the device. It is well known in the cardiac compression device art to provide a subxiphoid approach for implantation to avoid the complications associated with cutting through bone. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Walsh's invention through a subxiphoid approach to avoid the complications associated with cutting bone.

16. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh in view of Shapland et al. (US 6,425,856, hereinafter "Shapland"). Walsh discloses the essential features of the claimed invention except for delaying the drawing step by holding the ends apart with a biodegradable member incorporated into a spring and allowing the member to degrade. Shapland discloses a cardiac compression band that comprises delaying the drawing step by holding the ends apart with a biodegradable member incorporated into a spring and allowing the member to degrade (col. 12, lines 21-37) to allow the band to stay tight after the heart reverse-remodels. Therefore, it would have been obvious to one having ordinary skill in the art at the time

the invention was made to modify Walsh's invention by delaying the drawing step by holding the ends apart with a biodegradable member incorporated into a spring and allowing the member to degrade to allow the band to stay tight after the heart reverse-remodels.

### ***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chin (US 7,214,180) is one of many teaching of utilizing a subxiphoid approach.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

*MWK*  
8/7/07

*GEORGE R. EVANISKO*  
PRIMARY EXAMINER

5/9/7